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Multicentre Cancer Chemotherapy Group Randomised Trial of Adjuvant Chemotherapy for 'Early' Breast Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/01/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
B27

Study information

Scientific Title
Multicentre Cancer Chemotherapy Group Randomised Trial of Adjuvant Chemotherapy for 'Early' Breast Cancer

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Following initial local therapy, surgery with or without radiotherapy, patients are randomised to one of 2 treatment arms:
1. Arm A: Tamoxifen 10 mg twice daily for 12 months.
2. Arm B: A total of eight cycles of multidrug chemotherapy. Cyclophosphamide, vincristine and 5-fluorouracil to be given on day 1 and cyclophosphamide, vincristine and methotrexate on day 8 of each 3 week cycle.
3. Arm C: Multidrug chemotherapy with vincristine, methotrexate, chlorambucil and 5-fluorouracil repeated every 3 weeks for 8 cycles.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tamoxifen, cyclophosphamide, vincristine, 5-fluorouracil, methotrexate, chlorambucil

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Aged <70 years
2. Operable primary breast cancer with tumour <5 cm in greatest diameter
3. Histologically proven axillary nose involvement
4. Adequate renal and liver function
5. No prior history of other malignant disease
6. No previous chemotherapy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Action Cancer Belfast (UK)

Sponsor details
1 Marlborough Park
Belfast
United Kingdom
BT9 6XS
+44 (0)289 080 3344
abc@email.com

Sponsor type
Research organisation

Website
http://www.actioncancer.org

ROR
https://ror.org/02mf6dg38

Funder(s)

Funder type
Research organisation

Funder Name
Action Cancer Belfast (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration